

CLAIMS

1. A process for producing crystalline Form I of cabergoline, which process comprises the preparation of
5 toluene solvate Form V of cabergoline having the XRD powder pattern of Figure 2 by "reverse addition" and its conversion into crystalline Form I of cabergoline.
2. A process according to claim 1 in which the reverse
10 addition is the addition of toluene-cabergoline concentrate to cold heptane.
3. A process according to claim 1 in which the the
15 preparation of toluene solvate form V comprises dissolving raw cabergoline, or any mixture containing crystalline form of cabergoline including Form I crystals, in a suitable amount of a toluene at room temperature, adding the
20 resulting concentrate to cold heptane at temperatures below -10 °C, keeping under agitation the vessel containing heptane at temperatures below -10 °C and controlling the
intermittent addition rate for cabergoline concentrate to cold heptane in such a way that all the concentrate is not
25 added in less than 2 hours, stirring the resulting solution containing solid cabergoline and converting the resulting solvate form V into cabergoline Form I by de-solvation and drying process.
4. A process according to claim 3 in which the suitable
30 amount of toluene is from 2.5 to 4.0 g of toluene per gram of cabergoline.
5. A process according to claim 3 in which the suitable
amount of toluene is about 3.5 g of toluene per gram of cabergoline.

6. A process according to claim 2 in which the solution containing solid cabergoline is stirred to a temperature below -10°C for no more than three days.
- 5 7. A process according to claim 2 in which the resultant gel is quenched with cold heptane.
8. A process according to claim 2 in which the final drying is carried out by heating the solids of the solvate form V,
10 reducing the ambient pressure surrounding the solids, or combinations thereof.
9. A process for producing solvate form V of cabergoline having the XRD powder pattern of Figure 1 which process
15 comprises dissolving raw cabergoline, or any mixture containing crystalline form of cabergoline including Form I crystals, in a suitable amount of a toluene at room temperature, adding the resulting concentrate to cold heptane at temperatures below -10°C , keeping under
20 agitation the vessel containing heptane at temperatures below -10°C and controlling the intermittent addition rate for cabergoline concentrate to cold heptane in such a way that all the concentrate is not added in less than 2 hours, stirring the resulting solution containing solid cabergoline
25 and collecting the resulting solvate form V of cabergoline.
10. A process for producing crystalline Form I or crystalline Form V without the presence of any detectable amount of amorphous cabergoline, which process comprises
30 suspending Form V or Form I crystals under moderate agitation in pure heptane at a temperature of from 45° to 60°C for about 4 to 20 hours.

11. A process according to claim 10 characterized in that very small quantities of toluene are also added to the suspension in heptane of Form V or Form I crystals.